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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,643	03/23/2004	Aaron V. Kaplan	015471-000910US	3899

7590 07/05/2005

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EXAMINER
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GHERBI, SUZETTE JAIME J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/807,643

Applicant(s)

KAPLAN ET AL.

Examiner

Suzette J Gherbi

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6/10/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/10/05</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's amendment and response dated 6/10/05 has been received in application serial number 10/807,643.

#### ***Specification***

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There is no mention in the specification for the limitations of claim mentioned in claim 1 "...to extend axially into and expandably circumscribe at least one-half of the main vessel wall when the scaffold is implanted in the branch lumen with said one end adjacent the os" or as mentioned in claim 11, 23, 32 ".....to circumscribe at least a portion of the main vessel wall and open a passage through the anchors"

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-2, 5-8, 9-10, 12-17, 23-24, 27-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Yadav 6,096,071. Yadav discloses the invention as claimed comprising: A prosthesis for placement at an os opening with a radially expandible scaffold (10); and at least two circumferential anchors extending axially from an end of the scaffold (12) wherein the anchors are adapted to extend axially into and expandably circumscribe at least one-half of the main vessel wall when the scaffold is planted in the branch lumen; comprising at least three anchors; wherein the anchors are congruent; wherein the anchors radially expand when the scaffold is expanded; wherein a radiopaque marker is located at or near a transition location between the scaffold and the anchors. See col. 1, lines 61-67; col. 2, lines 14-15, 18-21, 28-30, 40-49; col. 4, lines 1-7. The intended use recitation/functional language of the claims carries no patentable weight in the absence of any distinguishing structure. Yadav clearly discloses the structure as claimed and is found to be inherently capable of performing the function.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3-4, 18, and 20-22, 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yadav in view of Richter 6,770,092. Yadav has been disclosed above however Yadav does not specify the lengths of the anchors or delivering another prosthesis through the main lumen scaffold. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the anchors to any desired length because it would provide tailor anchors for varying sized vessels or organs as noted in col. 4, lines 6-7 of Yadav. However, Yadav does not specify the delivery of another prosthesis. Richter teaches that a second stent (which is a prosthesis) can be deployed within the first stent. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the invention of Yadav and deploy a second prosthesis through the passageway and anchors because it would aid sections of vessels where multiple support was need a multiple branched regions.

7. Claims 32-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yadav in view of Sequin et al. 2003/0114912. Yadav has been described above as an expandable structure with at least two circumferential anchors extending axially from the scaffold however Yadav does not specify introducing another "prosthesis" within the passage through the anchors. Noting figures 18 Sequin et al. teaches that a first vascular prosthesis for supporting blood vessels have been known to be utilized for deploying additional prosthesis through the lumens after the first has been implanted see [0138]. It would have been obvious to one having ordinary skill in the art at the time

the invention was made to take the device of Yadav with an internal lumen opening and deploying a smaller second prosthesis through the lumen because it would allow the surgeon to support angles or bifurcated vessels in the location near the ostium.

### ***Response to Arguments***

8. Applicant's arguments filed 6/10/05 have been fully considered but they are not persuasive. Applicant has amended the claims can contends that the anchors of Yadav fail to teach *expandably circumscribing at least one half of the main vessel wall when the scaffold is implanted* as mentioned in claim 1. Applicant is reminded that claims 1-10, and 23-31 are product claims and not method claims. The structure as claimed is very broad and Yadav meet the structure as claimed and is capable of performing the functions. MPEP 2106 states:

The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. The following are examples of language that may raise a question as to the limiting effect of the language in a claim:

- (A) statements of intended use or field of use,
- (B) "adapted to" or "adapted for" clauses,
- (C) "wherein" clauses, or
- (D) "whereby" clauses.

This list of examples is not intended to be exhaustive.

9. It is the examiners opinion that the limited structure as claimed is met by the structure of Yadav and is capable of performing the structure especially if the device is


utilized in an anatomy with smaller sized vessels. After further evaluation claim 8 and 23 are also limited in structure and Yadav is capable of performing the function. For example the anchors of Yadav are bent or bend when the sheath is placed over the device for deployment and the surgeon can rotate the device with the anchor while they are loaded inside of the sheath (as the claim does not limit when or where this rotation may occur). The anchors of Yadav could also possible "rotate" if placed in an anatomy with larger vessels by turning the scaffold portion, which would in turn rotate the anchors. Applicant also contends the feature of "short flanges" as illustrated in Yadav. It is the examiners opinions that since the independent claims as currently written do not have limitations towards the lengths of anchors/flanges that the argument is moot. The claims with regards to the lengths have been addressed above in paragraph 7 and the rejection deemed proper.

10. With regards to the method claim limitations of 11 "*.. circumscribe at least a portion of he main vessel wall and open a passage through the anchors...*" this can be interpreted by Yadav because the anchors 12 circumscribe at least a portion of the tissue (18) that it is pressed/abuts against see mark up color coated copy enclosed. The newly added claims have also been addressed above.

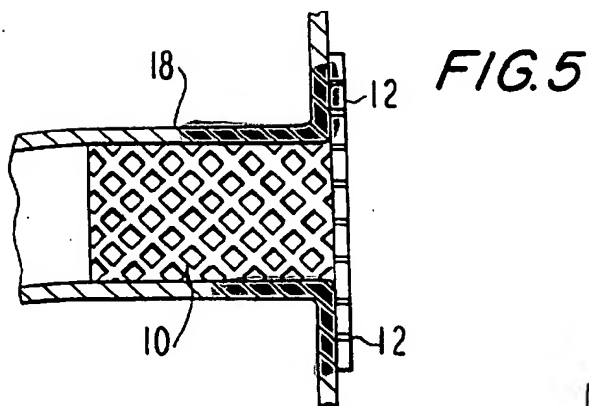
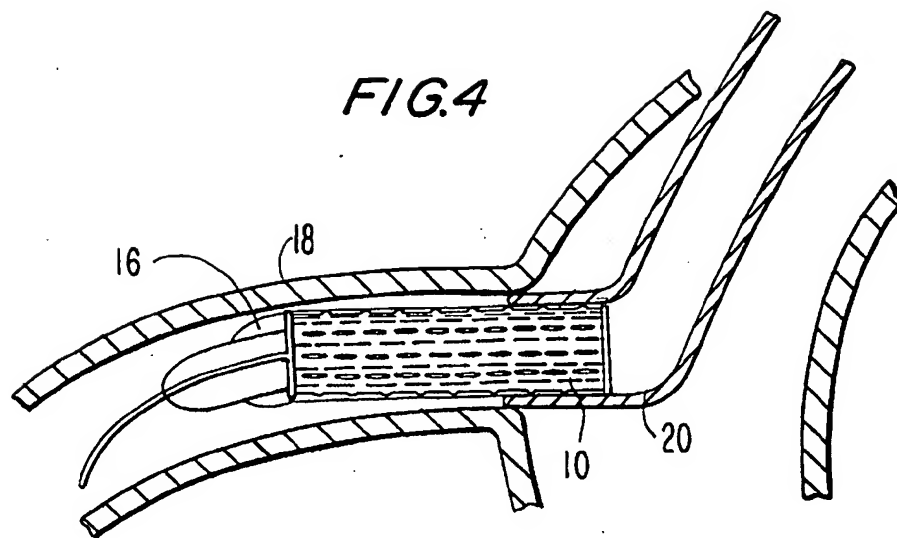
### ***Conclusion***

10. This office action is a second non-final because the prior objected to claim 8, 23 is now rejected due to lack of structural limitations and capability of Yadav's device to potentially perform the function as currently claimed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.
12. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.
13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

  
Suzette J-J Gherbi  
27 June 2005





**FIG. 6**

